

24TH ANNUAL



24TH LCI CONGRESS
OCTOBER 18-21

Serving and Celebrating Conditions of Satisfaction: A KBI Biopharma Case Study

John Lewis, Melisa Vasquez, Brian Belvin | ORB

LEAN GUMBO: THE RIGHT INGREDIENTS FOR PROJECT SUCCESS

October 20th, 2022

About Us



Introductions



John Lewis
Owner Project Director
35+ Years



Melisa Vasquez
Construction Project Manager
25+ Years



Brian Belvin PE PMP
Design Project Manager
15+ Years



About the Project



Project Overview

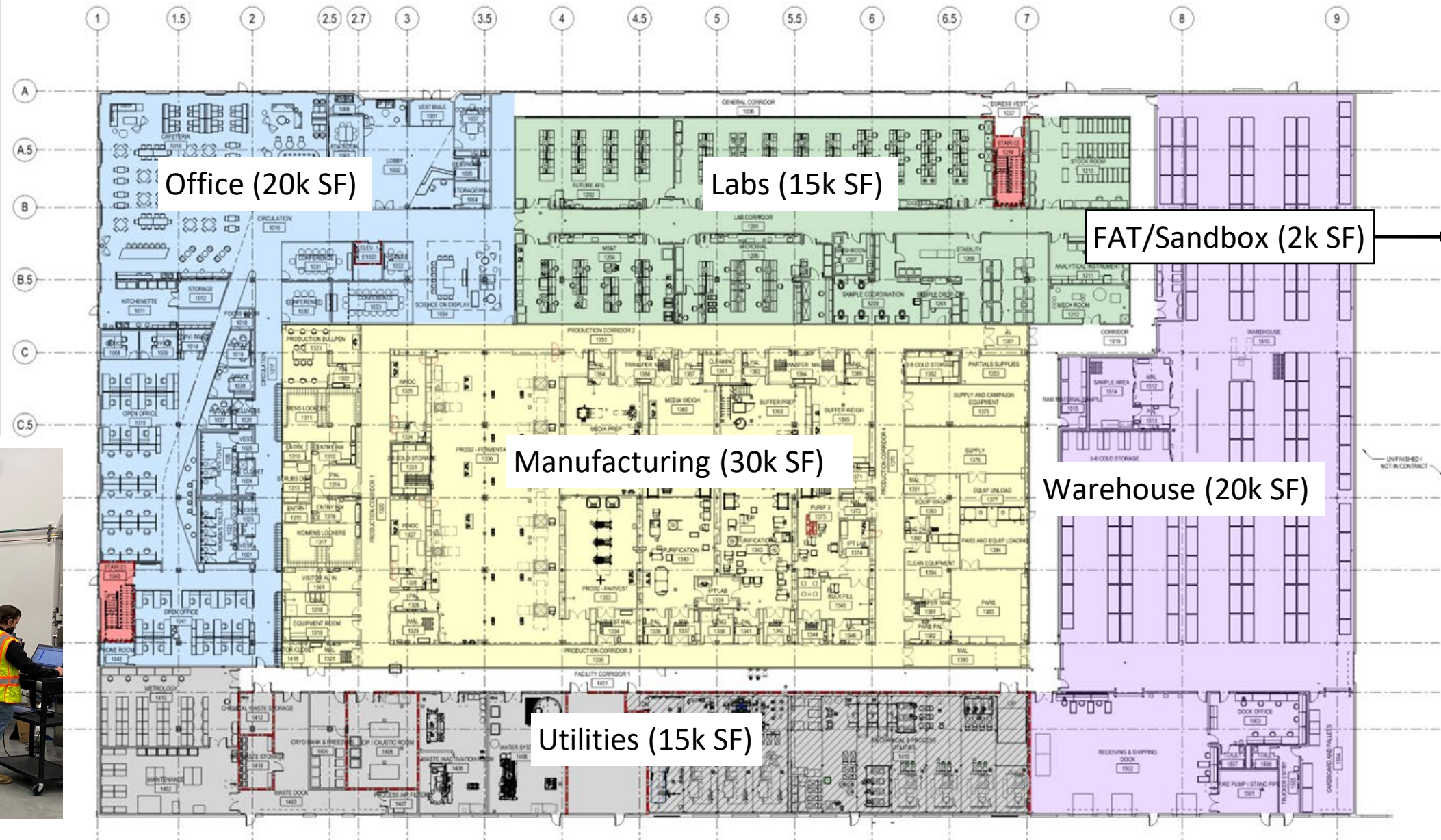
- Top 3 Business Drivers:**
1. Schedule
 2. Cost Certainty
 3. Operational Flexibility



Project Overview

Hybrid Facility

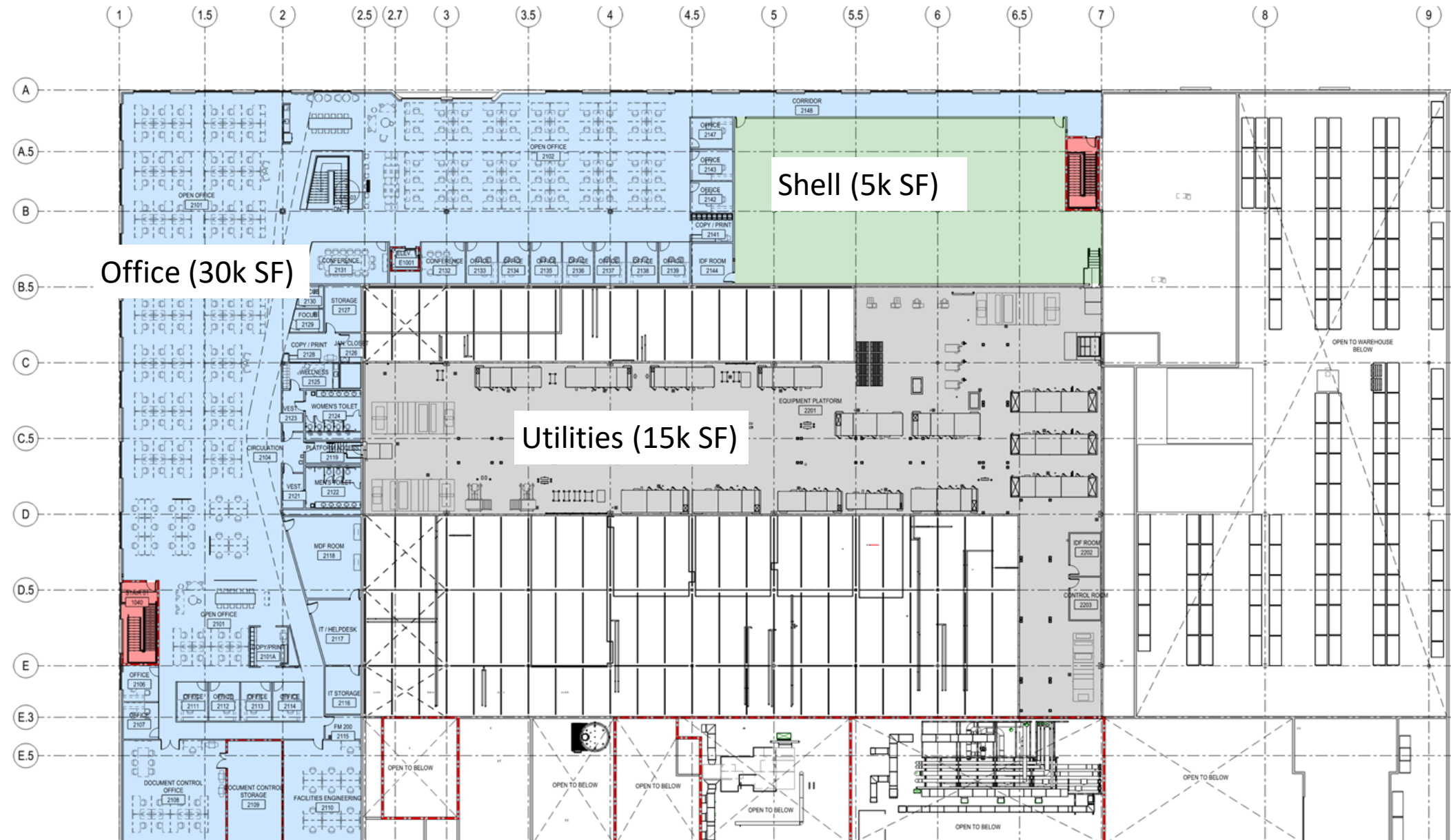
- 6x 2KL SU BRX - Mammalian CC
- BSL2, multi-product
- FDA, EMA, JP compliant
- 3000L SS Buffer Prep w/ CIP
- SS Caustic Delivery System
- Ozone Treated ambient WFI



Project Overview

Project Highlights

- Project Budget = \$155MM
- CRB TIC = \$142MM
- Total Fit Out = 150k SF
- \$947 / SF
- Completed process and utilities IOQs 20 months after starting concept design
- CRB's branded ONEsolution lean integrated project delivery method



Conditions of Satisfaction

BEHAVIORS

Have Fun

- Everyone meets their financial goals
- Recognition program to reward everyone individually and through teams
- Maintain work + life balance

Honor & Trust

- Act with sense of urgency
- Clearly define your commitment and conditions you expect to be met.
- Honor the commitments you make and be done when you say you will.
- Operate with deep levels of trust
- Be open to innovative ideas and try them

Communication

- Open, honest and real-time communication
- Access to technical minds in the field
- Get to know people
- Have a “see something say something” mindset

One Team

- Solve problems collaboratively, target zero RFIs
- Maintain overall positive team culture with mutual respect
- Maximize PPMOF by designing to fabricate in small batches.
- Keep Teams motivated

SUCCESS



OBJECTIVES

Criteria & Drivers

- Meets Pre-Engineering Lot Ready on 10/15/2021
- Meets GMP Eng Lot Ready on 12/10/2021
- Use TVD process to deliver less than maximum allowable cost of \$155MM
- Deliver a facility per the User Requirements Brief
- Make decisions and stick to them

Exceed Established Industry Standards

- ZERO recordables through weekly SOR participation with 1 per person per week
- High quality to minimize non-conformance through routine collaborative quality checks.

Maximize Efficiency & Utilization

- Use LPS to achieve PPC > 75%
- Seek out & eliminate waste

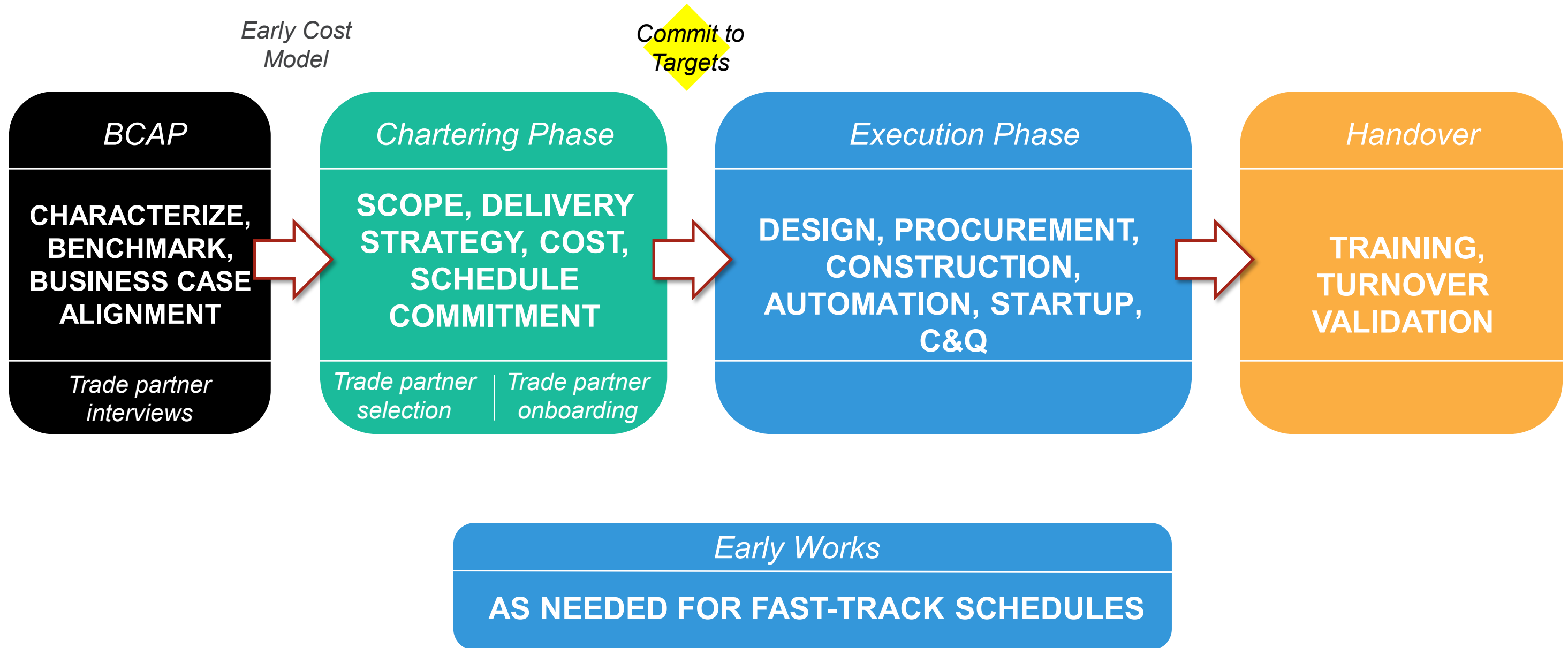
Create a Boundary-less Team that Challenges the Status Quo

- Plan and Design the work first in small batches – THEN – Fabricate & Install in small batches
- Maintain orderly work environments with just in time material management
- Use A3 thinking for system requirement definition





ONEsolution™ Delivery



Project Story (Metrics, Success)

Behaviors

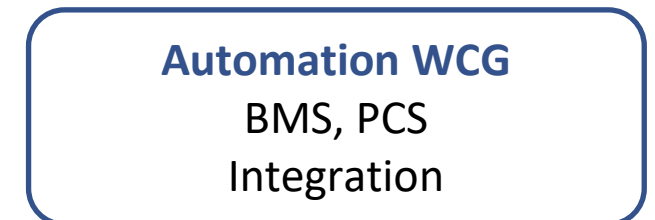
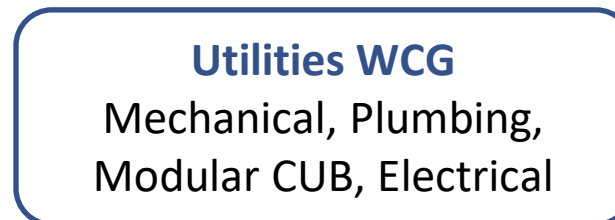
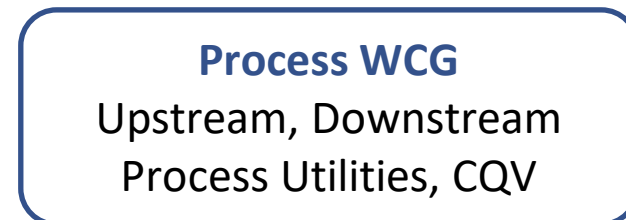
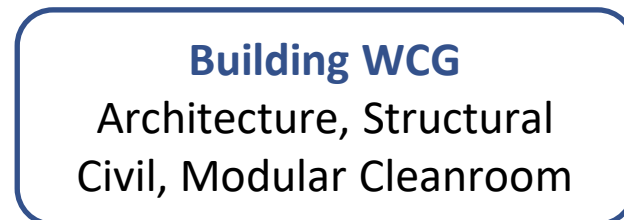
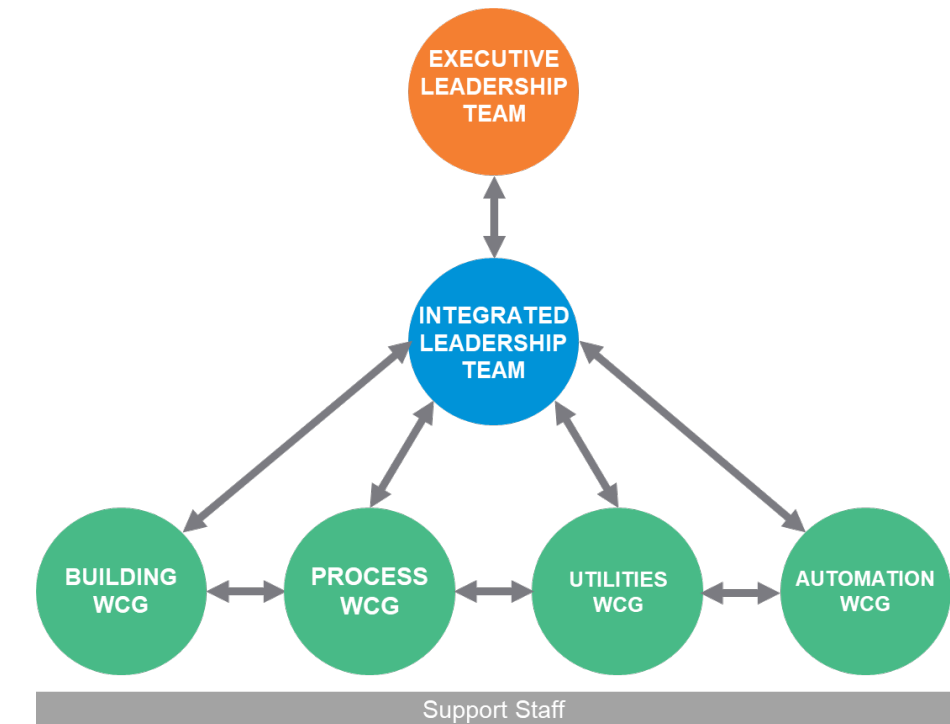
- Design phase was done 100% remote during COVID.
- Achieved Zero RFIs
- Maximized PPMOF, saving 9+ months on overall duration
- Robust "One Team" Safety Culture

Objectives

- We met our aggressive schedule goals and stayed below our cost Target while adding 50% additional production capacity.
- Minimal post-design release changes, almost no rework
- Cleanest jobsite EVER!
- Maximum financial incentive achieved – the entire team won



Project Organization



Obstacles and Achievements



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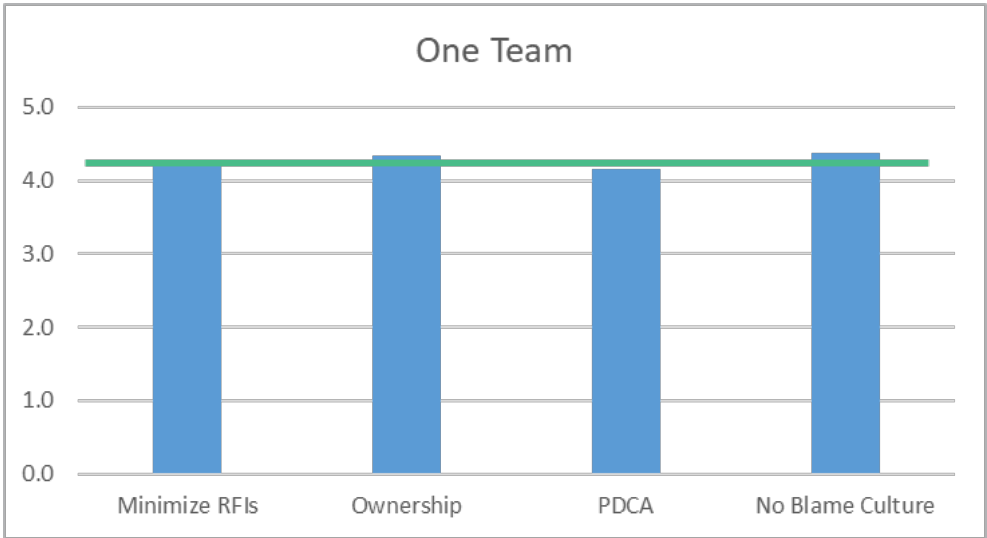
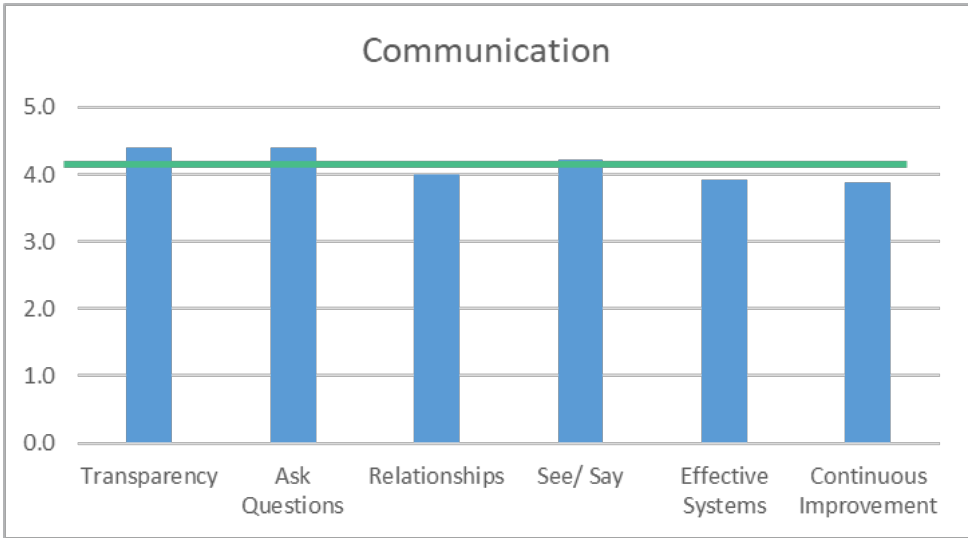
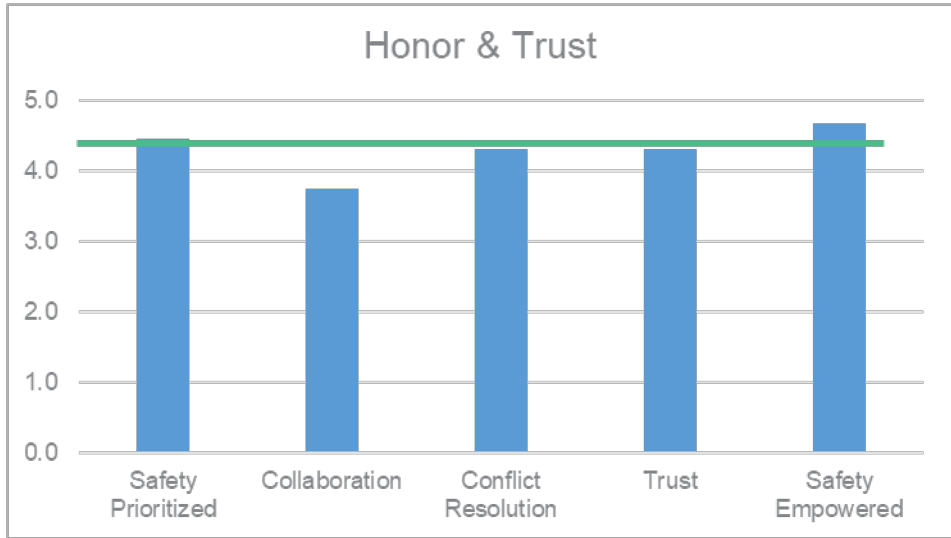
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Plan-Do-Check-Act: Plus/ Delta Surveys

<div><div>ENGINEERING ARCHITECTURE CONSTRUCTION CONSULTING</div></div> <div>Plus/ Delta Log</div>									
ID	Type	Event/ Subject	Description	Date Logged	Response Action	Owner	Target Date	Status	Add to Lessons Learned?



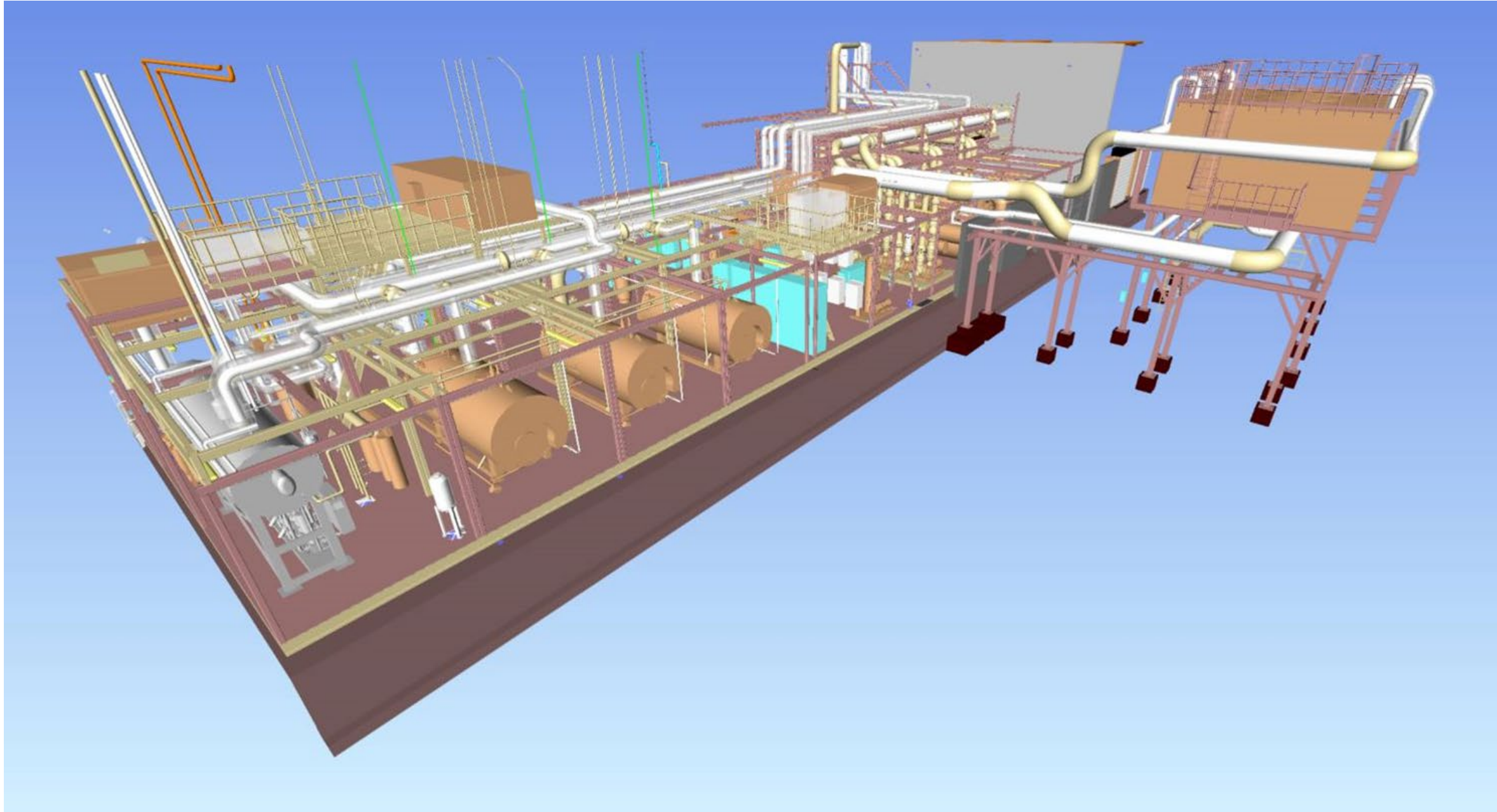
Finding Balance: Meeting Matrix

Meeting Matrix									
Time (EST)	Monday		Tuesday		Wednesday	Thursday		Friday	
8:00 AM - 8:30 AM	Huddles Placeholder		Huddles Placeholder		Huddles Placeholder	Huddles Placeholder		Huddles Placeholder	
8:30 AM - 9:00 AM	All Hands Huddle 8:45		All Hands Huddle 8:45		All Hands Huddle 8:45	All Hands Huddle 8:45		All Hands Huddle 8:45	
9:00 AM - 9:30 AM	Individual Working Time		I&C Huddle	CQV Huddle	Squad Check Placeholder WCG Ad Hoc Time when no Squad Check is scheduled	Clean Room Huddle	CQV Huddle	Individual Working Time	
9:30 AM - 10:00 AM						Open			
10:00 AM - 10:30 AM						Eq & Utilities WCG Breakout			
10:30 AM - 11:00 AM						Individual Working Time			
11:00 AM - 11:30 AM									
11:30 AM - 12:00 PM			Tech Ops Meeting			Individual Working Time			
12:00 PM - 12:30 PM	Lunch Hour - No Meetings Scheduled								
12:30 PM - 1:00 PM									
1:00 PM - 1:30 PM	Weekly Tech Ops		PMO Meeting (Schedule)		Ad Hoc PMO Time	PMO Meeting (Cost)		Ad Hoc PMO Time	
1:30 PM - 2:00 PM									
2:00 PM - 2:30 PM	Eq & Utilities WCG Breakout	Model Coordination Meeting	Building WCG (Coordination)		Model Coordination Meeting (All Hands)	Model Coordination Meeting (All Hands)		Individual Working Time	
2:30 PM - 3:00 PM									
3:00 PM - 3:30 PM	Building Breakout		Building Breakout		Equipment and Utilities WCG (Coordination)	Make Ready / Look Ahead			
3:30 PM - 4:00 PM									
4:00 PM - 4:30 PM	Mech. & Elec. Combined Huddle	Bi-Weekly Procurement Meeting	Individual Working Time		Individual Working Time	Mech. Huddle	Elec. Huddle		
4:30 PM - 5:00 PM						Individual Working Time			

Legend		
Meeting Group	Owner	Location
No Meetings Scheduled - Protected Time	Project Manager	-
Cross-Functional	Project Manager	Virtual
Owner's Internal Meeting	Owner	Virtual
Building WCG	WCG Lead	Virtual
PMO WCG	Project Manager	Virtual
Equipment and Utilities WCG	WCG Lead	Virtual
BIM/VDC/Modeling	WCG Lead	Virtual
Activity Owners/ Scheduling	LPS Facilitator	Virtual

Meeting Name	Attendance Required	CRB	Owner	TP1	TP2	Attendance Optional
Huddles Placeholder		Opt	Opt	Opt	Opt	
All Hands Huddle		X	X	X	X	
Equipment and Utilities WCG (Coordination)		X	X	Opt	Opt	
Eq & Utilities WCG Breakout		X	Opt	Opt	Opt	
Mechanical Huddle		X - Mech	X - Eng, Maint	-	-	
Electrical Huddle		X - Elect	X - Maint	-	X	
Mechanical & Electrical Combined Huddle		X - Mech	X - Eng, Maint	-	X	
Building WCG (Coordination)						
Building Breakout						
Clean Room Huddle						

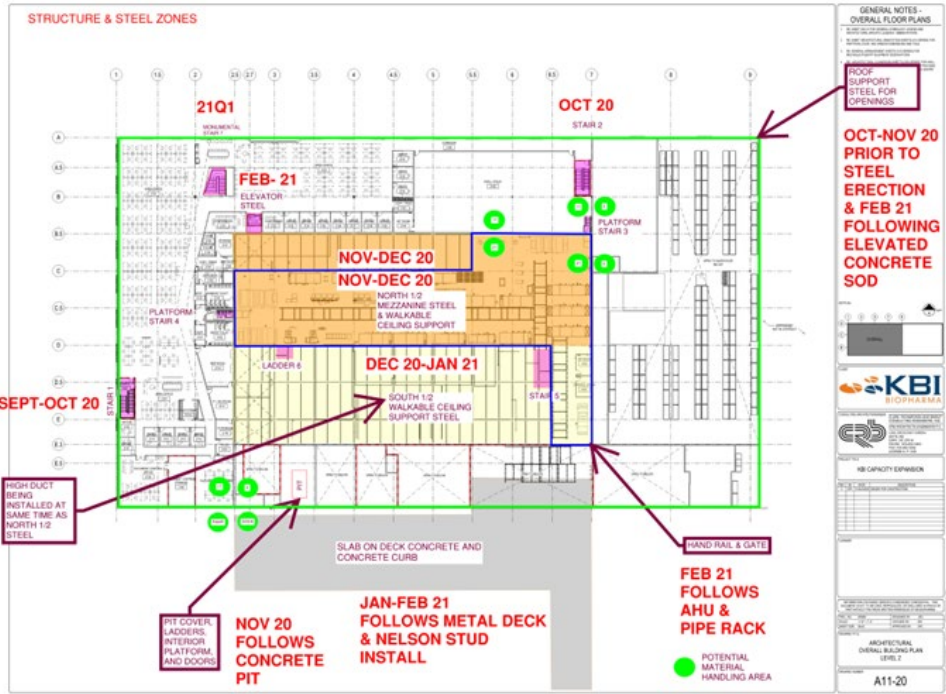
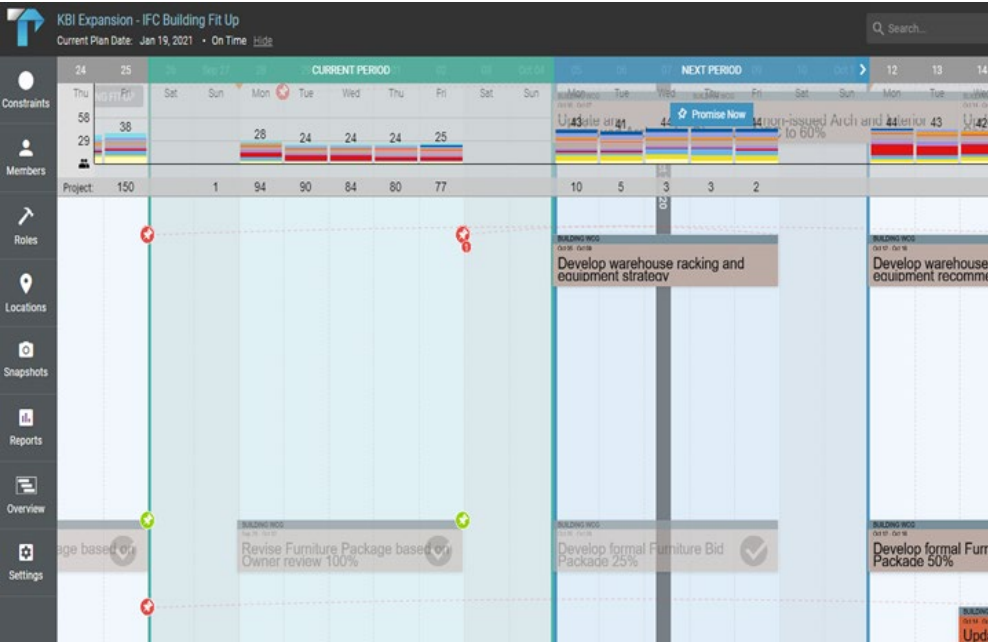
PPMOF



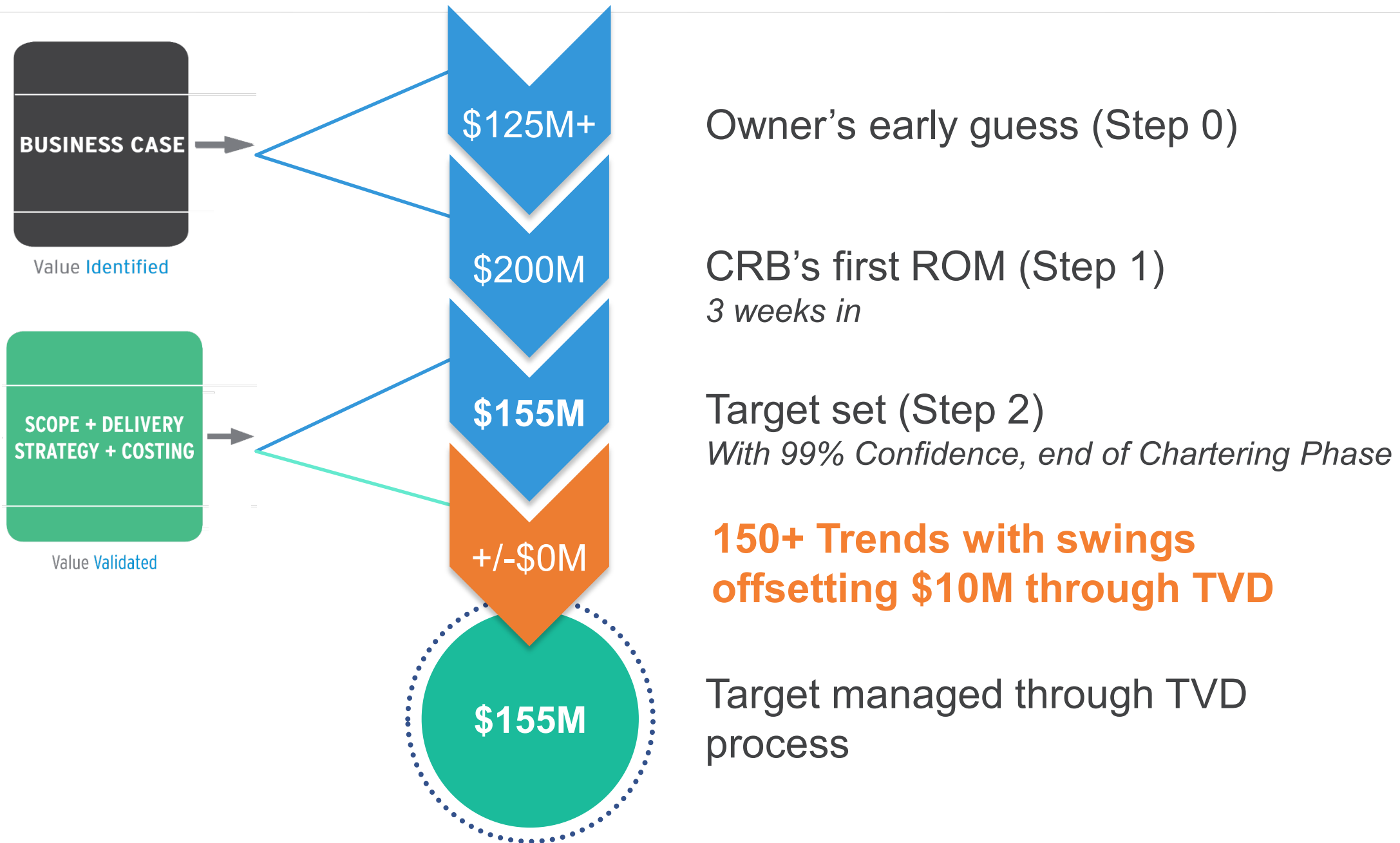
PPMOF



Last Planner System®



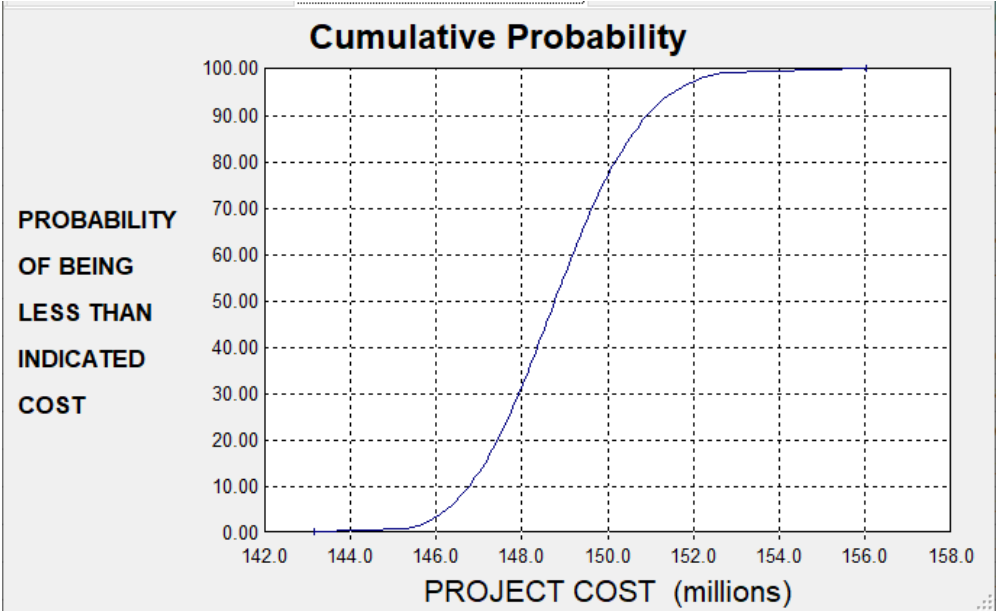
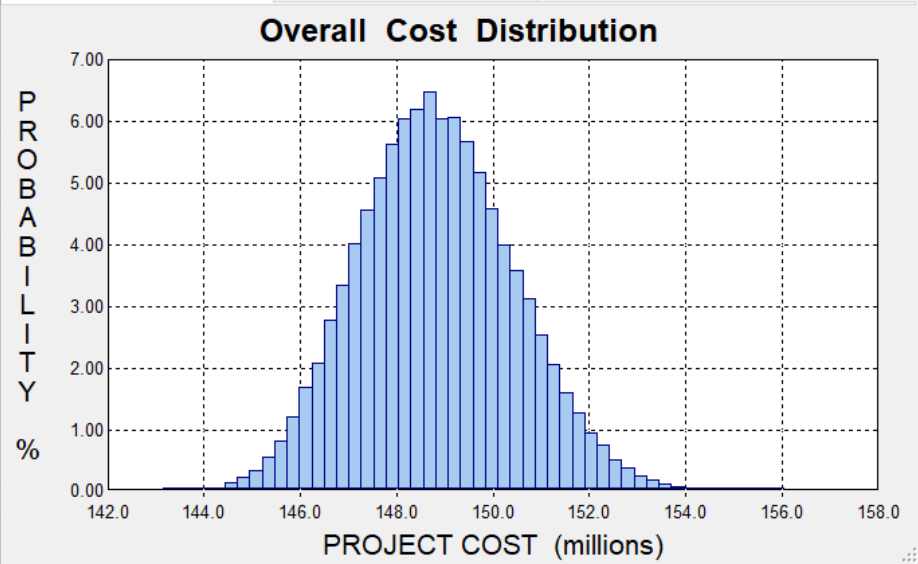
TVD by Phase



Setting the Target

CONTINGENCY ANALYSIS					
Sum of Likely Costs (SLC) :					1.40E+08
Probability of being less than SLC :					0.02%
Confidence Level	Total Project	Required Contingency			
Desired	Cost	Value	Percent of SLC		
100%	1.60E+08	12,089,961	8.40%		
99%	1.50E+08	8,761,104	6.09%		
95%	1.50E+08	7,624,191	5.30%		
90%	1.50E+08	6,995,624	4.86%		
80%	1.50E+08	6,247,132	4.34%		

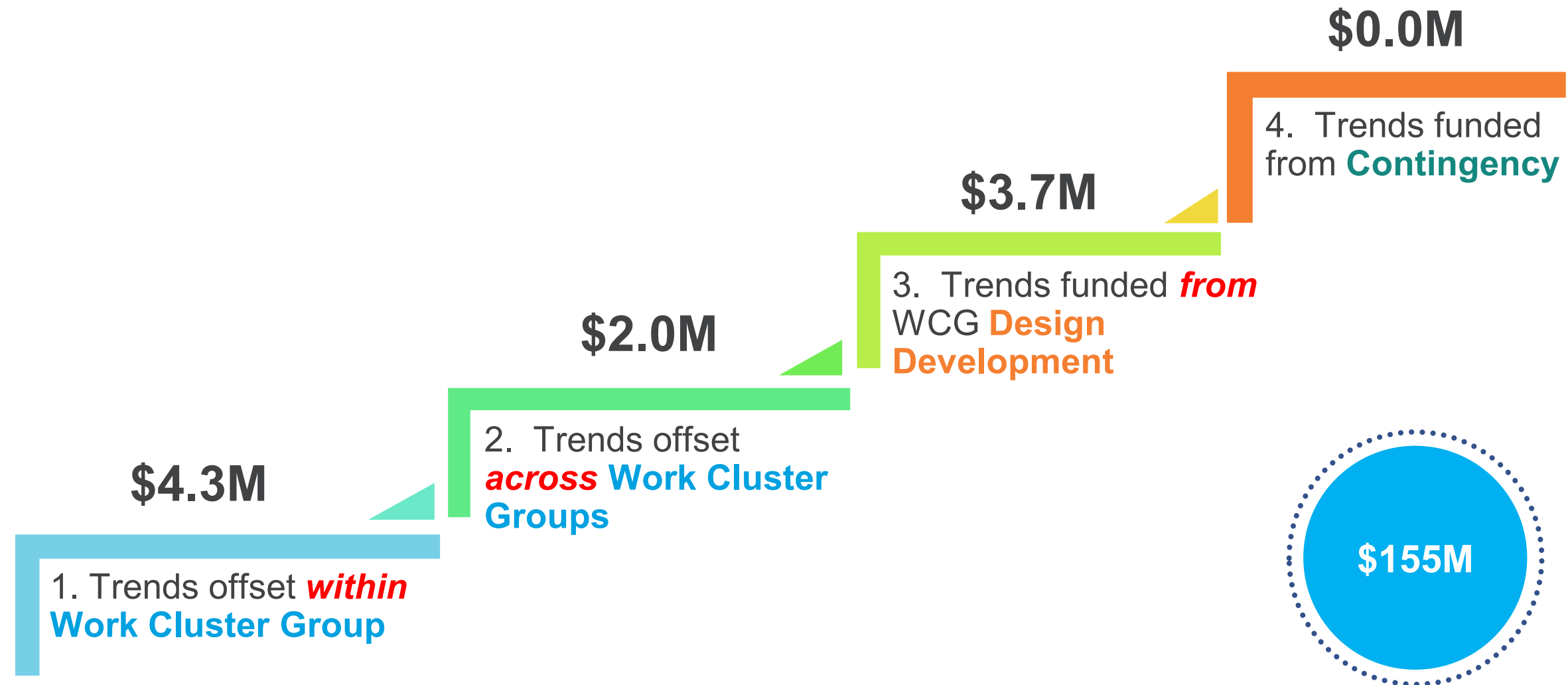
SENSITIVITY ANALYSIS		
Rank	Description	Expected Overrun
1	Escalation / Risk w.r.t. COVID	1,333,330
2	13 Special Construction	387,539
3	17 Process Control Systems	327,738
4	Process Equipment	317,602
5	15.2 Plumbing	254,485



Chartering Metrics: 60% of estimate details were trade partner provided
99.5% probability of success through Monte Carlo risk analysis



TVD Stair Slide

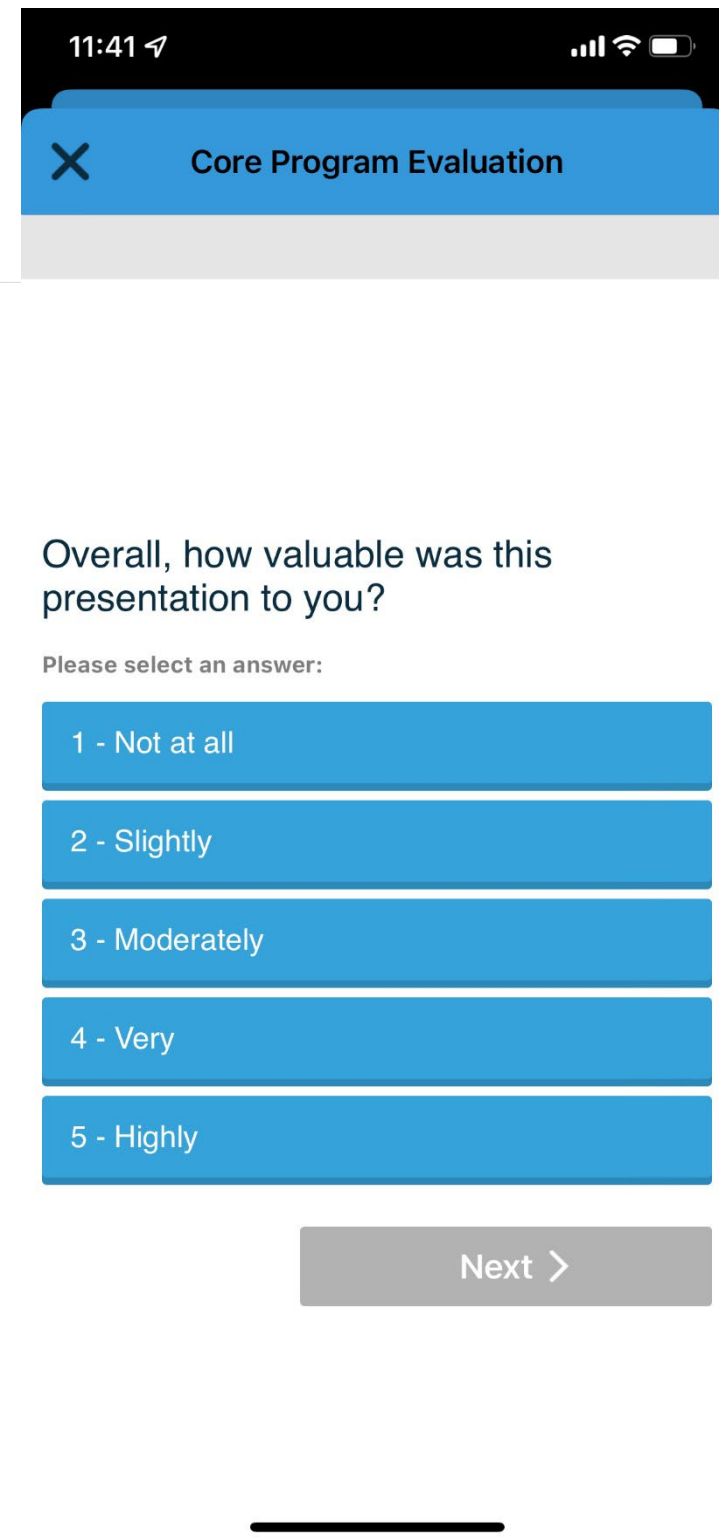
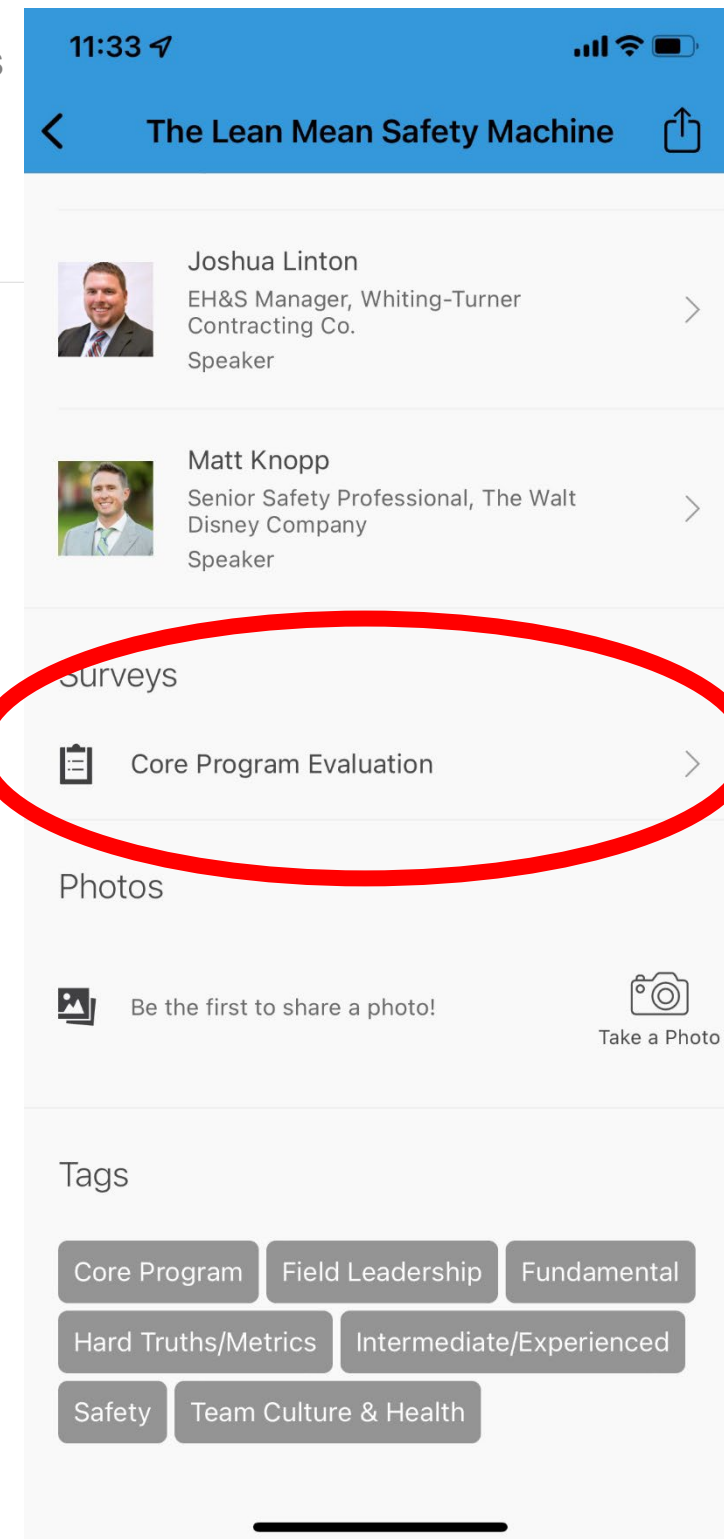


Rate Presentations in the App

Continuous improvement: give presenters your feedback by taking the session evaluation!

1. Find the session under “schedule”
2. Click on it then scroll down
3. Click “core program evaluation”
4. Complete the 5-question evaluation

This information will determine the top 5 presentation teams and the top Live Lab





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In the spirit of continuous improvement, we would like to remind you to complete this session's survey! We look forward to receiving your feedback.



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Thank you for attending this presentation. Enjoy the rest of the 24th Annual LCI Congress!

